UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL No. 1456
	)	Civil Action No. 01-12257-PBS
THIS DOCUMENT RELATES TO:	)	Subcategory No. 06-11337-PBS (Docket# 6316)
United States of America ex rel. Ven-a-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., Civil Action No. 07-CV-11618-PBS	)	Hon. Patti B. Saris

PLAINTIFF'S LOCAL RULE 56.1 STATEMENT OF UNDISPUTED MATERIAL FACTS

TABLE OF CONTENTS

Pursuant to Local Rule 56.1, Plaintiff, Ven-A-Care of the Florida Keys, Inc., hereby submits its Statement of Undisputed Material Facts in Support of its Motion for Partial Summary Judgment. To the extent any statement of fact herein is genuinely disputed, Plaintiff reserves the right to argue that the disputed fact is not material.

I. ABBOTT CORPORATION AND ITS PRODUCTS

1. Abbott Corporation at all times from 1991 until the present operated a division it called the Pharmaceutical Products Division ("Abbott PPD"). (Complaint ¶16) (Answer ¶16)

2. PPD sold all of the Erythromycin drug products (Erys) that are at issue in this lawsuit. These products are sold under 43 different NDCs depending upon packaging size, type and volume. These products are used to treat different types of infections. (Complaint ¶49, n.3)

3. While technically brand "innovator" drugs, all of these Ery products were sold by Abbott as "multi-source," generic drug products, which could be acquired from any number of competing pharmaceutical manufacturers, including Abbott. (Complaint ¶51) Beth Garvin-Senger Tr. 12/17/08 at 15:15-16:21. (Declaration of Susan Schneider Thomas in Support of Motion for Summary Judgment, hereinafter Thomas Exhibit 1.)

4. Most other PPD products, however, were sold as brand name drug products. Joseph Fiske Tr. 2/18/09 at 321:5 to 321:10. (Thomas Exhibit 2)

5. All of the named Ery products were generally eligible for reimbursement under Medicaid, since Abbott has a rebate agreement with CMS.

II. ABBOTT PRICE REPORTING PRACTICES

6. In the 1990's, Abbott's PPD reported AWPs for its products to the pricing compendia. *See* Kristen Minne Tr. 11/18/08 at 206:5-207:16, 227:9-228:13, 229:5-231:10 (Thomas Exhibit 46); Kristen Minne 11/18/08 Tr. Exhibit 22 (Thomas Exhibit 47), Minne

Exhibit 26 (Thomas Exhibit 48), Minne Exhibit 27 (Thomas Exhibit 49), Minne Exhibit 29 (Thomas Exhibit 50), and Minne Exhibit 31 (Thomas Exhibit 51). Thereafter, for all products sold by PPD, Abbott understood the published AWP was derived by the pricing compendia from Abbott's reported list price or WAC. For most products sold by PPD, Abbott reported a list price that was 5% above the actual wholesale cost paid (WAC) for the drugs. This was the practice since before 1991. Michael Sellers 30(b)(6) Tr. 3/31/08 Exhibits 33 (Thomas Exhibit 3) and Michael Sellers 30(b)(6) Tr. 3/31/08 Exhibit 34 (Thomas Exhibit 4). Abbott's corporate representative for PPD pricing issues testified that PPD used WAC as the price that a wholesaler generally pays for a product, the invoice price for the product, for most PPD products. Joseph Fiske Tr. 2/18/09 at 316-317 (Thomas Exhibit 2); *see also* Debra DeYoung Tr. 3/20/07 at 203-204 (Thomas Exhibit 5). It was only when Mr. Fiske was trying to explain why Abbott reported WACs that were *not* the prices at which wholesalers were invoiced for the Erys that he tried to draw a distinction between a "published wholesale acquisition cost" as compared to "what the wholesaler paid for the product, … the base deal price." Joseph Fiske Tr. 3/22/07 at 518-519 (Thomas Exhibit 55).

7. For some generic products sold by PPD, including the Ery products, Abbott deviated from its normal PPD business practice and reported prices to the pricing compendia that bore no reliable relationship to the actual prices at which wholesalers or others bought its drugs. Instead of reporting actual wholesaler invoice prices for the Erys, known as Base Deal prices, PPD concealed these Base Deal prices and reported inflated WACs. The practice of reporting WACs that were not the prices at which wholesalers were invoiced for Ery products began before 1993 and continued until at least July 2003. Joseph Fiske Tr. 2/18/09 at 318-319 (Thomas

Exhibit 2).

8. Market prices for the Ery drugs were not reported and were considered to be confidential. Beth Garvin-Senger Tr. 12/17/08 at 26:5 to 26:13 (Thomas Exhibit 1). No disclosure was made to Medicaid that the Ery products had invoice prices to wholesalers that were lower than published WACs (which were normally the invoice prices for PPD drugs). Beth Garvin-Senger Tr. 12/17/08 at 213:6 to 213:15 (Thomas Exhibit 1); Joseph Fiske Tr. 2/18/09 at 371:18 to 371:19 (Thomas Exhibit 2) (Abbott did not report a price lower than the inflated WAC price to the pricing compendia); Joseph Fiske Tr. 3/22/07 at 457:3 to 457:8 (Thomas Exhibit 13) (Abbott did not report base deal prices to pricing compendia); Joseph Fiske Tr. 3/22/07 at 516-517 (Thomas Exhibit 55) (catalogs and price lists that were sent to wholesalers with list and base deal prices were not sent to pricing compendia); Debra DeYoung Tr. 3/20/07 at 270:20 to 270:21 (Thomas Exhibit 5) ("PPD never submitted contract pricing to First DataBank").

9. There was no set or predictable relationship between the published prices for Ery drugs and the actual contract prices at which those drugs were sold. Beth Garvin-Senger Tr. 12/17/08 at 28:1 to 28:11 (Thomas Exhibit 1). Joseph Fiske Tr. 3/22/07 Exhibit 536 (Thomas Exhibit 9).

10. The Abbott employees responsible for reporting prices to the pricing compendia for PPD drugs, including the Ery products, had access to the bid schedule pricing that was used to invoice wholesalers. Joseph Fiske Tr. 2/18/09 at 361:6 to 361:10 (Thomas Exhibit 2).

11. Abbott, as a corporation, had another pharmaceutical division known as the Hospital Products Division ("HPD"). Abbott's HPD did not follow the same general practice as PPD. HPD reported a list price that was increased almost every year and that bore no

relationship to the declining market prices for the products. This HPD practice was similar to PPD's unique Ery practice. In 2001, however, Abbott HPD implemented new pricing policies, which required list price to be set at 5% above its real average wholesale price. (Draft – Catalog Price Adjustment – "The wide disparity in catalog prices and average market prices as currently configured is not supported by sufficient financial or market factors to survive scrutiny of public opinion.") (Abbott Exhibit 940 (Thomas Exhibit 87)) This is the same policy Abbott's Pharmaceutical Products Division had maintained since before 1991 except for Ery and some other multi-source products. Michael Sellers 30(b)(6) Tr. 3/31/08 Exhibits 33 (Thomas Exhibit 3) and Michael Sellers 30(b)(6) Tr. 3/31/08 Exhibit 34 (Thomas Exhibit 4). The change in HPD price reporting practices was, at least in part, the result of a government investigation into Abbott's price reporting conduct. Joseph Fiske Tr. 3/22/07 at 463:7 to 463:24 (Thomas Exhibit 55).

12. Joe Fiske, Abbott's corporate representative regarding PPD pricing, could not explain why the lower prices at which wholesalers were invoiced for Ery products were not the WAC prices that were reported to the pricing compendia, other than to say that the pricing compendia expected WAC and list pricing from manufacturers. Joseph Fiske Tr. 2/18/09 at 322:12 to 322:23 (Thomas Exhibit 2). The decision not to change the Ery product prices in 2001 with the HPD price changes was discussed in an agenda termed "Rules of the Road" prepared in connection with the HPD price changes. Mr. Mike Sellers, General Manager, Contract Marketing, wrote: "Per directions from last meeting: 1. Discussed price adjustment with other Divisions: PPD – Standard WAC prices at 5% below List; *potential exposure on Ery products which are sold at 40% to 60% below List*; some sales volume risk with low List price."

(emphasis added). Michael Sellers 30(b)(6) Tr. 3/31/08 Exhibit 33 (Thomas Exhibit 3); Joseph Fiske Tr. 2/17/09 Exhibit 13/Michael Sellers Tr. 4/12/07 Exhibit 590 (Thomas Exhibit 93). Sellers testified that the concern about sales volume risk was expressed by Joe Fiske. Michael Sellers 30(b)(6) 3/16/08 Tr. at 312:3 to 312:22 (Thomas Exhibit 88). Despite this perceived exposure from leaving the reported prices for the Ery products unchanged, that is precisely the path that Abbott chose.

13. When Abbott provided information on a new drug product to Texas Vendor Drug Program, it identified whether the drug was a generic or brand by indicating whether the product had been approved under an NDA or an ANDA. Debra DeYoung Tr. 3/20/07 at 231-232 (Thomas Exhibit 5). Similarly, price information sheets provided by Abbott to FDB or Red Book often contained notations as to whether the drug was brand or generic. *See* Kristen Minne Tr. 11/18/08 Exhibits 26 (Thomas Exhibit 48) and Minne 31 (Thomas Exhibit 51).

14. Abbott PPD employees knew that FDB published AWPs that were calculated at 25% above the WACs that Abbott reported. Beth Garvin-Senger Tr. 12/17/08 at 46-47 (Thomas Exhibit 1) ("In the pricing group, I would say that that was a general understanding."); Joseph Fiske Tr. 2/18/09 at 349:2 to 349:16 (Thomas Exhibit 2) (unit-dose packaging of Abbokinase only drug identified whose AWP was not calculated by FDB at 25% above WAC); Debra DeYoung Tr. 3/20/07 at 196:9 to 196:10 (Thomas Exhibit 5) (general understanding at Abbott that AWP was 125% of WAC); Kristen Minne Tr. 11/18/08 Exhibit 22 (Thomas Exhibit 47) and Minne Exhibit 24 (Thomas Exhibit 52). In training materials used within PPD, AWP was defined as "average wholesale price estimated at 125% of WAC by First DataBank." Debra DeYoung Tr. 3/20/07 Exhibit 507 (Thomas Exhibit 6); Beth Garvin-Senger Tr. 12/17/08 at 101-

102 (Thomas Exhibit 1). Similarly it was understood that if WACs were increased, then published AWPs would increase. Beth Garvin-Senger Tr. 12/17/08 at 184:7 to 184:16 (Thomas Exhibit 1).

15. Abbott employees in PPD understood and were trained that the AWPs published by FDB based on Abbott's reported prices were "used as a reimbursement reference for retail pharmacy." Debra DeYoung Tr. 3/20/07 Exhibit 507 (Thomas Exhibit 6); Beth Garvin-Senger Tr. 12/17/08 at 101-102 (Thomas Exhibit 1); Joseph Fiske Tr. 2/18/09 at 347:17 to 347:21 (Thomas Exhibit 2) ("We know that a number of third party payers have pricing reimbursement that's based on AWP"). This understanding extended to Medicaid reimbursement. Beth Garvin-Senger Tr. 12/17/08 at 115:12 to 115:22 (Thomas Exhibit 1); Debra DeYoung Tr. 3/20/07 at 176-177 (Thomas Exhibit 5) (knew that WACs published by FDB came from Abbott and that most Medicaid programs obtained pricing information from FDB). Abbott understood that it was important to Abbott's business that its drugs be eligible for Medicaid reimbursement, Beth Garvin-Senger Tr. 12/17/08 at 150-151 (Thomas Exhibit 1), Joseph Fiske Tr. 3/22/07 at 431:2 to 431:22 (Thomas Exhibit 55), and Abbott tracked the amount of business that was being reimbursed by Medicaid, including for the Ery products. Beth Garvin-Senger Tr. 12/17/08 at 164-165 (Thomas Exhibit 1).

16. Abbott employees in PPD understood that pharmacies were interested in AWPs because that was the basis on which they were reimbursed. Beth Garvin-Senger Tr. 12/17/08 at 112:2 to 112:17 (Thomas Exhibit 1). *See also*, ¶¶35, 37.

17. The prices at which Ery drugs within PPD were actually sold to wholesalers were called base deal prices. Joseph Fiske Tr. 2/18/09 at 318-319 (Thomas Exhibit 2). Base deal

prices were sometimes limited to wholesalers who met a certain threshold volume of sales, and then the price was extended throughout the year, and at other times base deal prices were invoiced without regard to volume. Joseph Fiske Tr. 3/22/07 at 382:3 to 382:23 (Thomas Exhibit 55). Even Abbott's corporate witness admits that, at most, approximately 5% of Ery products were sold at the published WAC prices. Joseph Fiske Tr. 2/18/09 at 370:16 to 370:22 (Thomas Exhibit 2). See also John Christopher Pavlik Tr. 1/22/09 at 40:4 to 40:11 (Thomas Exhibit 7) (instances when customers did not meet minimum orders to qualify for base deal prices were "rare").

18. Abbott employees were trained to consult the bid lists to obtain pricing in connection with solicitations, including for erythromycin products. Bid lists contained base deal prices, at least in 2000, 2001, 2002 and 2003. Donna Arnold Tr. 12/18/08 at 83-84; 91:5 to 91:8 (Thomas Exhibit 8). These base deal prices bore no consistent relationship to reported WAC or list prices, or to published WACs or AWPs, except that the base deal prices were almost always lower. Beth Garvin-Senger Tr. 12/17/08 at 28:1 to 28:11; 41-42 (Thomas Exhibit 1); Joseph Fiske Tr. 2/18/09 at 319:9 to 319:12 (Thomas Exhibit 2) (Abbott billed wholesalers for Ery's at prices lower than published WACs). Abbott routinely sent customers price lists that compared Abbott's list prices or estimated AWPs with the base deal prices. Joseph Fiske Tr. 3/22/07 at 514-515 (Thomas Exhibit 55); Fiske Tr. 3/22/07 Exhibit 536 (Thomas Exhibit 9); Debra DeYoung Tr. 3/20/07 at 191:10 to 191:21 (Thomas Exhibit 5). Russell Lehn Tr. 1/15/09 at 127-130 (Thomas Exhibit 10).

19. Prices from wholesalers to pharmacies were, in turn, lower than the low base deal prices. Beth Garvin-Senger Tr. 12/17/08 at 41-42 (Thomas Exhibit 1). When wholesalers sold

to customers at prices below the base deal prices at which the wholesalers had been invoiced, chargebacks were processed to account for the differences. Joseph Fiske Tr. 2/18/09 at 353-354 (Thomas Exhibit 2). Because of these chargebacks, the net amount paid by the wholesaler was less than the invoiced, base deal price. Joseph Fiske Tr. 2/18/09 at 353-354 (Thomas Exhibit 2). Abbott was aware that wholesalers had programs in effect that offered prices to pharmacies that were significantly less than the reported WACs. Joseph Fiske Tr. 3/22/07 at 495-496 (Thomas Exhibit 55).

20. Base deal pricing for Ery drugs was discontinued in about 2003. Beth Garvin-Senger Tr. 12/17/08 at 201:16 to 201:21 (Thomas Exhibit 1). Although wholesalers were then billed at WAC prices, the sometimes very large difference from pharmacy prices was still accounted for through chargebacks. Beth Garvin-Senger Tr. 12/17/08 201-202 (Thomas Exhibit 1); Beth Garvin-Senger Tr. 12/17/08 Exhibit 13 and John Christopher Pavlik Tr. 1/22/09 Exhibit 17 (Thomas Exhibit 11).

21. Abbott calculated its average sales prices on at least a monthly basis, based on WAC sales less rebates, discounts, return goods allowance and any other billing adjustments. Beth Garvin-Senger Tr. 12/17/08 at 66-67 (Thomas Exhibit 1).

III. ABBOTT'S FAMILIARITY WITH MEDICARE AND MEDICAID AND REIMBURSEMENT[1]

22. As early as 1996, Abbott established a group called the "Medicare Working Group", which was comprised of individuals from various parts of Abbott, including HPD, PPD, Ross, and Abbott's government relations/lobbying group, among others, who met or conferred telephonically on a periodic monthly basis. Haas at 53:10-13; 56:4-6; 61:20-21; 62-65; 66:1-5 & Haas Exhibit 1121; J. Miller 52:8-22; 53:1; Tootell 73:3-16. (Lavine Dec. Exhibits 110, 111, 112)

23. In December 1996, Medicare Working Group received a document that had been referenced in a Medicare Working Group meeting by Michael Tootell. The document was entitled "Medicare Part B Payment For Drugs Average Wholesale Price Issue" and put the group on notice of the following:

a. "Currently, Medicare pays for those drugs that are not reimbursed on a prospective basis or a cost basis at the lesser of the average wholesale price or the actual acquisition cost of the drug …. Medicare pays at the average wholesale price level, because the program has not acquired

[1] Because much of the evidentiary record applicable to these claims has already been set out at length in the briefing on the motions for summary judgment in the United States' Abbott action, VAC attempts to avoid duplication by cross-referencing those filings wherever appropriate. Accordingly, references are made herein to the Lavine Declarations (Docket Nos. 6302, 6305, 6308, 6312 and 6323), Henderson Declaration (Docket No. 6310) and exhibits thereto, the Declaration of Mark G. Duggan, Ph.D. (Exhibit 41 to Henderson Declaration (Docket 6310) in Support of the United States' Motion for Partial Summary Judgment (Docket No. 6318), and to the United States' Local Rule 56.1 Statements of Undisputed Facts (Docket Nos. 6316 and 6321) (referenced, as in the federal cases, as US-A-SF for the Statement of Facts pertaining to Abbott, and US-C-SF, for the United States Common Statement of Facts), all of which were filed by the United States in connection with the Motion for Summary Judgment against Abbott.

acquisition cost information sufficient to establish reimbursement rates."

b. "There have been several studies and investigations into the appropriateness of using AWP as the determining factor for payment. The common conclusion of these efforts is that the use of AWP as a payment measure results in excessive reimbursement that is far out-of-line with the estimated acquisition costs of the drugs …."

c. "[T]here is some evidence that often the AWP for a drug is set at a particular level to establish third-party reimbursement, but has no relevance to any party beyond the third-party payer [sic]. For these reasons, the AWP issue is being presented and considered not as a program policy issue, but rather as an issue steeped in fraud, abuse and waste."

d. "[N]umerous people from within the industry have conceded publicly that AWP makes little sense as a basis for reimbursement."

e. "While AWP may be in excess of the acquisition cost of a drug (plus a reasonable markup), it does enable pharmacists to be reimbursed, albeit indirectly, for the necessary pharmaceutical services they do in fact provide. Since Medicare does not acknowledge the existence of these services, and thus does not provide for separate or additional reimbursement for them, the current use of AWP is the only means of paying pharmacists for what they actually do for Medicare beneficiaries."

Abbott Medicare Working Group document ABT 53263-53265. (Lavine Dec. Exhibit 97)

24. One Ross Products division employee, Mr. Michael Tootell, expressed his concern to Abbott in-house legal counsel about the legal exposure and potential negative consequence of AWP spreads. Tootell 199:17-22; 200:1-20; 202:1-11. (Lavine Dec. Exhibit 112)

25. PPD personnel were aware of the role that AWP spread played in influencing a providers' choice of which product to utilize when there were therapeutic alternatives. Among the discussions had by the Medicare Working Group, when PPD members Don Buell and Don Conway were both present, there was a discussion of a possible pricing change by some state programs for Lupron, to acquisition cost. Tobiason Tr. 3/28/07 Exhibit 546 - Notes dated 1/29/97. (Thomas Exhibit 12) The notes from the meeting indicate that this would present a problem for Abbott because it would take all the providers' profit out of prescribing Lupron and would result in providers instead dispensing the lower cost Zoladex product.

26. On October 31, 2000, Abbott's Miles White received a letter from Congressman Fortney "Pete" Stark which stated, among other things, the following:

> "The evidence amassed by Congress clearly shows that Abbott has intentionally reported inflated prices and has engaged in other improper business practices in order to cause its customers to receive windfall profits from Medicare and Medicaid when submitting claims for certain drugs.
>
> "Contrary to Abbott's recent assertions in the national media, the price manipulation conduct was in no way required by or consistent with existing reimbursement laws or policies. Indeed, Abbott did not falsify published prices in connection with other drugs, where sales and market penetration strategies did not include arranging financial 'kickbacks' to health care providers." (Lavine Dec. Exhibit 66, Stark Oct 31, 2000 Letter to Miles White, page 1)

27. Abbott testified that prior to 2003 it did not understand that the False Claims

Act's reach included liability for reckless or inadvertent conduct in its price reporting. Fishman 30(b)(6) 3/20/08 at 643:10-22; 644:1-10. (Lavine Dec. Exhibit 91)

28. Abbott never sought guidance from HCFA, CMS or HHS-OIG about Abbott's pricing activities or to verify whether its pricing activities violated any law, including the federal False Claims Act. Abbott never asked Medicare or Medicaid officials whether it was permissible to provide customers with spread or AWP information. Fishman Rule 30(b)(6) 3/12/06 at 224:4-22; 225:1-6; 234:14-20; 240:10-22; Fishman 30(b)(6) 3/20/08 at 644:11-14. (Lavine Dec. Exhibits 90, 91). PPD representative Joe Fiske testified that Abbott did not rely on any government reports in determining how to report its Ery prices. Joseph Fiske Tr. 2/18/09 at 285:25 to 286:7. (Thomas Exhibit 2)

29. The only review Abbott undertook to evaluate whether its pricing practices complied with Medicare and Medicaid fraud and abuse laws was undertaken by its legal department. Abbott has claimed that the evaluation is privileged and instructed its counsel not to answer questions concerning the evaluation. Fishman 30(b)(6) 3/12/08 at 335:5-22; 336-343; 344:1-22. (Lavine Dec. Exhibit 90)

30. Abbott also refused, on the grounds of privilege[2], to provide testimonial evidence from its corporate representative concerning:

a. whether Abbott evaluated the legality of the spreads between its actual selling prices to customers and its AWPs;

[2] The United States specifically sought a Rule 30(b)(6) designee from Abbott to testify on efforts undertaken by Abbott to comply with federal and state law. Abbott designated David Fishman, an in-house Abbott lawyer, who refused upon instruction of Abbott counsel to answer many questions on the grounds of attorney-client privilege or on the grounds that the question called for a legal conclusion.

b. advice regarding AWP, spread or spread marketing provided by Abbott in-house counsel to Abbott employees (even though non-legal employees were not permitted to review or interpret federal and state statutes and regulations); and

c. advice regarding price reporting and Medicare and Medicaid fraud and abuse (including concerning the federal Anti-kickback statute and the federal False Claims Act) provided by Abbott in-house counsel to Abbott employees.

Fishman 30(b)(6) 3/12/08 at 31:20-22; 32:5-22; 33:1-19; 35:7-22; 36-39; 40:1-18; 42:20-22; 43-46; 47:1-8; 110:8-22; 111:1-7; 287:7-16; 295:2-22; 296; 297:1-21; 332:10-22; 333:1-22 (Lavine Dec. Exhibit 90).

31. In 2001, TAP Pharmaceuticals ("TAP") pled guilty to federal criminal charges ("TAP Criminal Case") in the District of Massachusetts, settled a civil action, and entered into a Corporate Integrity Agreement with HHS-OIG as a result of conduct including creating and marketing high spreads. TAP paid a criminal fine of $290,000,000 and civil settlement payment of $559,482,560 incident to settling two related AWP lawsuits filed in the District of Massachusetts ("TAP Civil Actions"). In 2001, Abbott had to sign a letter agreement consenting to the criminal plea and settlement. *See* Abbott Letter Agreement in TAP Case (Lavine Dec. Exhibit 94).

IV. MARKETING SPREAD

32. Abbott understood the needs of its target customers. Debra DeYoung Tr. 3/20/07 Exhibit 507, Pricing 101 (Thomas Exhibit 6); Joseph Fiske Tr. 3/21/07 at 130:18 to 130:22

(Thomas Exhibit 13); Abbott Laboratories, Pharmaceutical Products Division, 2004 Customer Business Development Plan, ABT_ERY-E00018196-20 (Thomas Exhibit 14); Public Health Policy & Strategy Update, ABT_ERY-E00005954-65 (Thomas Exhibit 15); Abbott Trade Sales & Development, Trade Project Summary Report 7/11/2005, ABT_ERYE00017027-30 (Thomas Exhibit 16); Amerisource Bergen customer profile, ABT_ERY-E00006011-30 (Thomas Exhibit 17); McKesson customer profile, ABT_ERY-E00005976-88 (Thomas Exhibit 18); CVS Account Overview, ABT_ERY-E00005000-04 (Thomas Exhibit 19); Abbott Laboratories, Pharmaceutical Products Division, 2004 Customer Development Plan, Kroger, ABT_ERYE00018228-36 (Thomas Exhibit 20); 2008 Trade Channel Situation Analysis, ABT_ERYE00001087-1124 (Thomas Exhibit 21); 2005 Trade Sales & Development Strategic Plan Summary, ABT_ERY-E00006305-26; National Trade Executives Humira Talking Points, ABT_ERY-E00006043-63 (Thomas Exhibit 22).

33. Various supply chain partners communicated their business interests and concerns to Abbott, describing the capabilities and benefits of partnerships between Abbott and these companies. Abbott learned these business partners were able to provide valuable market intelligence and services to assist Abbott in achieving sales. Through these business relationships, Abbott attempted to enhance its market share through marketing efforts and managerial decisions. Leader Drug Stores Advantage, Russell Lehn Tr. 1/15/09 Exhibit 15 (Thomas Exhibit 23); Theresa Parker Tr. 2/19/09 at 112-113 (Thomas Exhibit 24), Parker Exhibit 6 (Thomas Exhibit 25); Retail Buying Group Documents, Russell Lehn Tr. 1/15/09 Exhibit 11 (Thomas Exhibit 26); Potential Issues and Talking Points, ABT_ERY-E00011616-17 (Thomas Exhibit 27); the Health Strategies Group, Specialty Pharmacy Management Industry

Overview and Assessments of Leading Companies, TXTABT-E 0060660-90 (Thomas Exhibit 28); Cardinal Health document, Michael Beck Tr. 9/27/06 Exhibit 157, TXABT 34886-904 (Thomas Exhibit 29); Option Care document, Dennis Walker Tr. 4/5/07 Exhibit 581, TXABT 60942-70 (Thomas Exhibit 30); Pharmaceutical Buyers Inc. (PBI) document, Sellers Tr. 2/14/07 Exhibit 293, TXABT 453403-13 (Thomas Exhibit 31); Managed Healthcare Associates (MHA) document, Sellers Tr. 2/13/07 Exhibit 292, TXABT 370566-68 (Thomas Exhibit 32); GeriMed document, Susan Rhodus Tr. 4/26/05 Exhibit 332, TXABT 15660-63 (Thomas Exhibit 33); GeriMed document, Susan Rhodus Tr. 4/26/05 Exhibit 335, TXABT 12280-315 (Thomas Exhibit 34).

34. Abbott, including PPD, developed its knowledge of third party reimbursement in several ways, including:

- employees such as Ms. April Gerzel, PPD Supervisor of Chargebacks and Memberships, and Ms. Donna Arnold, PPD Contract Analyst, who both had experience in Abbott's Home Infusion business. (Donna Arnold Tr. 12/18/08 at 10-31 (Thomas Exhibit 8)); (April Gerzel Tr. 2/20/09 at 6 (Thomas Exhibit 35));
- the employment of reimbursement experts such as Mr. Heggie (HPD Manager, Reimbursement), Ms. Tobiason (Senior Director of Corporate Reimbursement), Mr. Rodman (HPD Home Infusion Services, Reimbursement Supervisor), Mr. Tootell (Ross, Senior Manager for Health Policy and Reimbursement) and Ms. DeYoung (PPD, Senior Manager of Strategic Pricing);
- participation in the Medicaid rebate and Supplemental rebate system (April Gerzel Tr. 2/20/09 at 13 (Thomas Exhibit 35));

- Abbott's experience as a provider in the home infusion market; Abbott's various business relationships and partnerships including pharmacy providers, group purchasing organizations and wholesalers (Cardinal Health Rx Management Conference, ABT_DOJ-E00017188-206 (Thomas Exhibit 36)); and
- from industry sources such as the National Pharmaceutical Council and the American Society of Consultant Pharmacists (ASCP) through reports made available to companies like Abbott (ABT_ERY-E00007713-50 (Thomas Exhibit 37)).

35. Abbott's knowledge of reimbursement issues included the concept of reimbursement spread and that generic buyers considered reimbursement spread in choosing which products to purchase. Debra DeYoung Tr. 3/20/07 Exhibit 507, presentation "Pricing 101" (Thomas Exhibit 6) or Beth Garvin-Senger Tr. 12/17/08 Exhibit 4 (Thomas Exhibit 38); Theresa Parker Tr. 2/19/09 at 133-135 (Thomas Exhibit 24); Pavlik e-mail, MAC List from Aetna for Ery's and Cyclosporine, ABT_ERY-E00009460-62 (Thomas Exhibit 39); Potential Issues and Talking Points, ABT_ERY-E00011616-17 (Thomas Exhibit 27).

36. Abbott was aware of possible reimbursement changes and attempted to impact these changes by perpetuating the current reimbursement system. Cynthia Sensibaugh Tr. 7/12/07 Exhibit 1120, ABT-DOJ 295990-92 (Thomas Exhibit 40); Rosemary Haas Tr. 8/30/07 at 29-32 (Thomas Exhibit 41); Richard Rieger Tr. 8/9/07 at 27-39 (Thomas Exhibit 42); Medicare Working Group Documents; Lobbying Documents ABT-DOJ 0295979 – 80 (Thomas Exhibit 43); David Landsidle Tr. 10/15/07 Exhibits 1138 {ABT-DOJ 296200} (Thomas Exhibit 44) and 1139 {ABT-DOJ 295996} (Thomas Exhibit 45); Rodman E-mail, Exhibit 963, TXABT 434310

(Thomas Exhibit 53). The Medicare Working Group at Abbott was created to examine Medicare and reimbursement issues, including AWP. This working group, according to Mr. Reiger, Manager of Strategic Planning at Abbott (corporate) was created to be a "crossdivisional" group within Abbott. Richard Rieger Tr. 8/9/07 at 16 (Thomas Exhibit 42). PPD's representation on this group included Mr. Don Buell, Director of Health Economics and Policy and Dr. Don Conway, Director of Epidemiology and Outcomes Research. Virginia Tobiason Tr. 3/28/07 Exhibit 546(a), 546(b); Medicare Working Group Documents (Thomas Exhibit 12).

37. Abbott was aware that its customers were interested in AWP and customers asked Abbott to provide to them AWP information. Joseph Fiske Tr. 3/21/07 at182-183 (Thomas Exhibit 13); John Christopher Pavlik Tr. 1/22/09 at 128-129 (Thomas Exhibit 7). Abbott was also aware customers generally did not pay WAC or AWP for the Ery drugs, neither of which are representative of prices being paid in the marketplace. In fact, Abbott routinely transacted business with its customers based on contract or base deal prices and Abbott did not report these contract prices, or report lower prices when contract prices declined, to the compendia. John Christopher Pavlik Tr. 1/22/09 at 182-183 (Thomas Exhibit 7); Debra DeYoung Tr. 3/20/07 at 291-292 (Thomas Exhibit 5); Joseph Fiske Tr. 3/22/07 at 486:15 to 486:25 (Thomas Exhibit 55); Russell Lehn Tr. 1/15/09 at 62-63 (Thomas Exhibit 10); Debra DeYoung Tr. 3/20/07 at 78-79 and 191-192 (Thomas Exhibit 5); Bid Sheets, Debra DeYoung Tr. 3/20/07 Exhibits 510 (Thomas Exhibit 57), DeYoung Exhibit 511 (Thomas Exhibit 58), DeYoung Exhibit 512 (Thomas Exhibit 59), DeYoung Exhibit 513 (Thomas Exhibit 60), DeYoung Exhibit 514 (Thomas Exhibit 61), DeYoung Exhibit 515 (Thomas Exhibit 62), DeYoung Exhibit 516 (Thomas Exhibit 63), DeYoung Exhibit 517 (Thomas Exhibit 64) DeYoung Exhibit 518 (Thomas Exhibit 65); John

Christopher Pavlik Tr. 1/22/09 Exhibits 17 (Thomas Exhibit 11) and Pavlik Exhibit 18 (Thomas Exhibit 66).

38. Abbott understood how customers made pricing decisions based on reimbursement. The "Neoral Profit Analysis" presented a spreadsheet calculation of net profit to a provider, for Neoral compared to Gengraf. The testimony of Abbott witnesses was that this was an internal analysis, but it demonstrates an understanding of the importance of this type of reimbursement-profit analysis in marketing a generic drug. While this comparison was not made for the drugs at issue in this case, the calculation was based on AWP, an estimated reimbursement rate and actual product acquisition costs, and demonstrated a working knowledge of reimbursement profitability. Joseph Fiske Tr. 2/18/09 Exhibit 21 (Thomas Exhibit 67).

39. Customer documents informed Abbott of the significance of spread in customer buying decisions. For example, a 1996 GeriMed Request for Proposal, from Abbott business records, prepared for bidding pharmaceutical manufacturers and suppliers (Susan Rhodus Tr. 4/26/05 Exhibit 335) (Thomas Exhibit 34) demonstrated spread was important to GeriMed members.

40. Mr. Tim Bien of Omnicare (Timothy Bien Tr. 4/25/05 Exhibit 302) (Thomas Exhibit 68) demonstrated the importance of spread to Abbott's customers with his request (Timothy Bien Tr. 4/25/05 Exhibit 301, TXABT 42077) (Thomas Exhibit 69) in May of 2001 to be made "whole" by Abbott (HPD) after a $10.5 million loss that Omnicare experienced after the 2000 DOJ price changes and the May 2001 HPD price decreases. About this time, Omnicare sponsored a "Pharmaceutical Industry Day" bringing in manufacturer representatives from across the country to present to the pharmaceutical industry issues important to Omnicare resulting

from decreased levels of reimbursement. Timothy Bien Tr. 4/25/05 at 103-104 (Thomas Exhibit 70). Mr. Dave Molnar, PPD's National LTC Manager, attended Omnicare's Pharmaceutical Industry Day. Timothy Bien Tr. 4/25/05 Exhibit 313 (Thomas Exhibit 71).

41. Other customer documents also demonstrated that Abbott was concerned about customer reimbursement. In an October 7, 2002, email to Abbott (Debra DeYoung Tr. 3/20/07 Exhibit 509, TXABT-E 0033830 (Thomas Exhibit 72)) Mr. David King of Safeway wrote: "*I believe your company has a genuine concern for our reimbursement….*" Abbott was aware from Cardinal documents in Abbott's possession that spread and reimbursement were topics addressed by Cardinal to its customers. Joseph Fiske Tr. 3/21/07 at 153-156 (Thomas Exhibit 13)

42. Customers asked for and Abbott provided AWP information. By combining AWP information, obtained from Abbott and other sources, with acquisition costs, customers had the necessary information for determining a product's spread. This allowed customers to optimize their profitability with respect to purchasing decisions. Multiple computer systems, including Abbott's own CHIP system (see also, for example, GeriMed Emphasys, Susan Rhodus Tr. 4/26/05 Exhibit 351 (Thomas Exhibit 73)) provided either a direct calculation of the spread or provided AWP and price so that spread could be easily calculated. Cardinal's corporate representative, Donald Lyle, testified at length on this topic and described pharmacies' widespread use of software to evaluate reimbursement and spreads. Donald Lyle Tr. 7/22/08 at 138-140, 161 & 181-188. (Thomas Exhibit 74)

43. Fiske testified, as the PPD representative, that Abbott understood that pricing compendia calculated AWPs they published off of WAC prices that Abbott reported, and that many Medicaid programs set their reimbursement based on the published AWPs. Joseph Fiske

Tr. 3/21/07 at 76 – 81 (Thomas Exhibit 13). Abbott PPD provided AWP information to customers at least before the AWP policy was adopted. Joseph Fiske Tr. 3/21/07 at 108-109 (Thomas Exhibit 13). Abbott, including PPD, was aware that some customers evaluated the reimbursement amount they would receive, i.e., the spread, when determining which products to purchase. Joseph Fiske Tr. 3/21/07 at 122-123 (Thomas Exhibit 13); (when Abbott decided not to lower Ery prices in 2001, Fiske indicated there could be negative sales volume impact if reported prices were lowered) (Michael Sellers Tr. 3/16/08 30(b)(6) at 243-246) (Thomas Exhibit 88). Prior to Abbott's 2004 policy against providing AWP information, Abbott did provide AWPs when requested by customers in the contracting context. Joseph Fiske Tr. 3/21/07 at 174-176 (Thomas Exhibit 13). Abbott was involved in preparing and generally familiar with documents re Gengraf that depict spread or reimbursement margin. Joseph Fiske Tr. 3/21/07 at 250-253 (Thomas Exhibit 13).

44. PPD was responsible for marketing Gengraf, the Erythromycin product line, and the Ross division's Pediazole. These drugs were marketed as generic medications. In contrast, most of the PPD product line was comprised of single source medications which were marketed based, in part, on clinical features and the marketing was focused on prescribing physicians and managed care organizations. Abbott marketed the Erythromycin products differently than other PPD products by focusing the sales message to drug purchasers rather than prescribers and emphasized low purchase prices including the "base deal" price. (Joseph Fiske Tr. 2/18/09 at 346-347 (Thomas Exhibit 2); Debra DeYoung Tr. 3/20/07 Exhibit 520, TXABT 244823-843 (Thomas Exhibit 75))

45. Abbott communicated to customers its low Ery prices and the associated AWPs

used to determine reimbursement spreads. For example, Debra DeYoung Tr. 3/20/07 Exhibit 520 (Thomas Exhibit 75) revealed how Abbott carefully considered and analyzed its Erythromycin pricing to its customers. In this 1995 memo concerning various retail buying groups, Bob Rochelle, the Assistant Market Manager for Managed Care, discussed various tiered pricing for different Abbott Ery products to chain and retail buying groups (RBGs). A memo describing Abbott's RBG Mail Order Program listed as its objective the influencing of RBG member pharmacies to order Abbott erythromycin products. Attached as part of the circulated packet were templates on Abbott letterhead for the RBGs to use promoting Abbott Ery products to their members based on a comparison between the listed, published AWPs for the products and the price that the RBG member would pay to obtain the product. Debra DeYoung Tr. 3/20/07 Exhibit 520, TXABT 244843 (Thomas Exhibit 75). For example, the list included AWPs for Ery Filmtabs of $21.92, $104.12 and $189.57 for the 100, 500 and 1000 size packages respectively, while prices listed elsewhere in the packet for the RBG for the same products were $12.95, $62.82 and $121.75, less approximately 10% further discounts off list for high percentage utilization. Ery Tabs, NDC 6304-13, 6304-53 and 6321-13, for different strengths and package sizes, were listed with AWPs of $6.45, $31.29 and $14.30, while the price list for the RBGs listed $23.75, $112.81 and $40.10 for the same products, again with additional discounts noted. Debra DeYoung Tr. 3/20/07 Exhibit 520, TXABT 244843, 244832 (Thomas Exhibit 75).

46. In about 2003, competition for the Ery line in the marketplace decreased and Abbott took price increases on some of the Ery products ranging from about 20 percent to 150 percent on the Erythromycin base, Erythromycin stearate and Ery-Tab. (Joseph Fiske Tr. 2/17/09

at 48-49) (Thomas Exhibit 54) Prices were not increased on all the Erythromycin products, but Abbott decided to discontinue base deal pricing completely. Joseph Fiske Tr. 2/17/09 at 48-49 (Thomas Exhibit 54). Joseph Fiske Tr. 2/17/09 Exhibits 2 (Thomas Exhibit 76) Fiske Exhibit 3 (Thomas Exhibit 77) and Fiske Exhibit 4 (Thomas Exhibit 78). Mr. Fiske originally testified the Ery prices were changed due to government investigations into pricing, but, two years later he amended his testimony and stated that he no longer believed the government investigation was the reason for the Ery price changes. Joseph Fiske Tr. 2/17/09 at 213-214 (Thomas Exhibit 54) The discontinuation of base deal pricing was significant in that prior to the 2003 Ery price changes, wholesalers were routinely invoiced at base deal prices and after this time wholesalers were invoiced at WAC. Joseph Fiske Tr. 2/17/09 at 87-88 (Thomas Exhibit 54) From July 2003, to this day, PPD reports WACs for the Ery products that are not representative of prices being paid in the marketplace by pharmacies or costs to wholesalers.

47. Abbott made pricing information, including AWP pricing, available in the marketplace in many ways, (April Gerzel Tr. 2/20/09 at 20-21 (Thomas Exhibit 35)) including: the reporting of prices to the Medicaid Administrators (April Gerzel Tr. 2/20/09 at 21-35 (Thomas Exhibit 35); Theresa Parker Tr. 2/19/09 at 60-61 (Thomas Exhibit 24)); price reporting to the pricing compendia (Joseph Fiske Tr. 2/17/09 Exhibit 9 (Thomas Exhibit 79); April Gerzel Tr. 2/20/09 at 23-25 (Thomas Exhibit 35)); discussions between Abbott sales personnel (and Trade Relations) and customers Joseph Fiske Tr. 3/21/07 at 102, 108, 176, 216 (Thomas Exhibit 13); Theresa Parker Tr. 2/19/09 at 56-58 (Thomas Exhibit 24); through retail stocking sheets (Joseph Fiske Tr. 2/18/08 at 317 (Thomas Exhibit 2); Debra DeYoung Tr. 3/20/07 at 191 (Thomas Exhibit 5)); responses to customer bid requests (Joseph Fiske Tr. 2/18/09 at

317(Thomas Exhibit 2)); pharmaceutical wholesalers; and group purchasing organizations (April Gerzel Tr. 2/20/09 at 21-48 (Thomas Exhibit 35)).

48. Various group purchasing organizations, retail buying groups (RBGs) and wholesalers (such as Cardinal Health, McKesson and Amerisource Bergen) communicated market price and spread information about Abbott's products to their customers through value added services. These services included, for example, computer programs such as the GeriMed "Emphasys" software and the "CardinalSource" preferred generic program. Abbott was aware of the capability of the marketplace to provide pricing information to providers, including spread comparisons. Cardinal Health presentation (Michael Beck Tr. 9/27/06 Exhibit 157, TXABT 34886 (Thomas Exhibit 29), at slide 9; the Pharmaceutical Buyers, Inc. (PBI) "Missed Opportunity" report capability (Michael Sellers Tr. 2/14/07 Exhibit 293, TXABT 453403 (Thomas Exhibit31)); Managed Healthcare Associates, Inc. (MHA) promotional piece describing the AccuSpread program, VTP083-4880; MHA Associates, Inc. December 1, 2000, letter (Michael Sellers Tr. 2/13/07 Exhibit 292, TXABT 370566 (Thomas Exhibit 32)), in which MHA tells Abbott that MHA is sending out a request for proposals where MHA will make two awards, "*one for the lowest cost and one for the best spread.*" Further, Abbott created business relationships with and communicated pricing information with these supply chain partners. (April Gerzel Tr. 2/20/09 at 35-37 (Thomas Exhibit 35)) Through these business relationships, Abbott was able to increase awareness of the reimbursement spreads important to its customers.

49. In a marketing planning document (John Christopher Pavlik Tr. 1/22/09 Exhibit 1) (Thomas Exhibit 80) Abbott describes the steps to be completed in preparing a new product launch including marketing tools such as a Market Information Sheet, a New Product

Information Sheet, and a Wholesale Stocking Sheet. The Wholesale stocking sheet included within the set of tasks to be completed with respect to the product launch, price reporting to state Medicaid's and the compendia. Further, the Wholesale pricing sheet was to contain pricing columns including 'estimated AWP' and a blank 'wholesale price' column.

50. In about 2004, a general policy was put in place at Abbott prohibiting discussions of spread with customers. (Joseph Fiske Tr. 3/21/07 at 85 (Thomas Exhibit 13); Joseph Fiske Tr. 2/18/09 Exhibit 20 (Thomas Exhibit 81)). Ms. Tobiason, who worked on developing the policy, could not recall any prior policy prohibiting reimbursement and spread discussions. In addition to the policy document, storyboards (Joseph Fiske Tr. 3/21/07 Exhibit 523, TXTABT-E 0065053-68 (Thomas Exhibit 82)) for training modules prepared and used by Abbott trained employees on this policy as well as other fraud and abuse issues. This is consistent with Abbott employees who testified that after this point in time they no longer discussed AWP with customers. However, as noted above, there were mechanisms established in the marketplace that continued to enable pharmacies to identify and evaluate reimbursement spreads without the need for Abbott to explicitly discuss this issue with its customers.

V. USE OF ABBOTT TRANSACTIONAL DATA TO CALCULATE ACTUAL PRICES

51. Throughout the relevant time period, Abbott maintained large spreads between its published prices for Ery products and the prices at which customers actually purchased those products. See Declaration of Ian Dew and Exhibits thereto.

52. Ven-A-Care's expert, Mark G. Duggan, analyzed the transaction data produced by Abbott in this case. The transaction data is a copy of the data used by Abbott in the ordinary course of business. Among other things, Dr. Duggan used Abbott's transaction data to analyze

the prices at which Abbott products were being sold directly by Abbott to customers and the prices at which the Abbott products were being re-sold by wholesalers and distributors to end customers.

53. The damages calculations performed by Prof. Duggan took into account the use of MACs or FULs by State Medicaid programs. The methodology essentially "readjudicated" each of the claims in the same manner as would have been done under the applicable reimbursement algorithm if the more accurate prices been reported by defendants. *See* Declaration of Mark G. Duggan, Ph.D., in Support of the United States' Motion for Partial Summary Judgment, ¶¶ 43-46 (Exhibit 41 to Henderson Declaration (Docket No. 6310)).

54. There were wide variations in both the dollar amount and the percentage calculation of spread for any given NDC (*See, e.g.*, Dew Exhs. 1, 10, and 15, showing, respectively, dollar spread ranges for specific NDCs of $7.95 - $14.68 and percentage spreads from 60.57% to 153.71%; $11.62 - $18.52 and 98.91% to 255.55%; $5.72 - $8.00 and 165.95% to 413.78%). Within a given drug code, the percentage spread often varied significantly for different package sizes. (*See, e.g.*, Dew Exhs. 29-31, for NDCs 00074-6346-19, -20, and -38, respectively, showing spread percent ranges from 122.05% - 179.22%; 78.24% - 172.42%; 74.41% - 125.65%). Even at a given point in time, the spread percentage could vary markedly within a drug code. (Again, looking at NDC 00074-6346-19, -20, and -38, depicted on Dew Exhs. 29-31, the percentage spread on the different size packages ranged from 134.04% to 132.76% to 88.79% in 1996 quarter 1, from 126.15% to 143.13% to 74.41% in 1998 quarter 1, and from 122.58% to 170.80% to 78.30% in 2002 quarter 1). In parallel litigation previously proceeding in Texas state court, Abbott submitted an expert report acknowledging the extreme

difficulty of the government (or other third party payors) procuring actual acquisition costs and needing instead to work from published or reported prices. *See* Report of Marv Shepherd ¶¶ 21, 29 and 43 (Thomas Exhibit 94).

VI. THE MEDICAID PROGRAM

55. Medicaid is a joint federal-state program to assist the poor, elderly, and disabled in obtaining medical care. 42 C.F.R. § 430.0 (2009). Under the Medicaid Act, which is Title XIX of the Social Security Act, 42 U.S.C. §§ 1396 - 1396v, the federal government provides financial support to states that establish and administer state Medicaid programs in accordance with federal law through a state plan approved by the U.S. Department of Health and Human Services ("HHS"). 42 U.S.C. § 1396; 42 C.F.R. §§ 430.0, 430.10 - 430.20 (2009). One requirement is that the states have a State Plan that includes a methodology for reimbursing health care providers, including pharmacies and other providers that dispense drugs to Medicaid enrollees. 42 U.S.C. §§ 1396a(a), 1396d(a). A declaration authenticating the state plans produced by the United States in this case is attached to the United States' Local Rule 56.1 Statement of Undisputed Material Facts submitted with the Common Brief on Summary Judgment. Henderson Common Declaration. (Henderson Common Exhibit 44 (Declaration of William S. Lasowski))

56. Federal regulations require that state Medicaid programs' payment for drugs not subject to Federal Upper Limits not exceed, in the aggregate, the estimated acquisition cost of the drug plus a reasonable dispensing fee established by the agency. 42 C.F.R. § 447.331. For purposes of this regulation, the term "estimated acquisition cost" was defined as "the agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold

by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers." 42 C.F.R. § 447.301. This definition did not change during the relevant time period and was also incorporated into many State regulations concerning reimbursement for Medicaid drugs.

57. State Medicaid program employees attempted to determine EAC in accordance with the federal regulation defining EAC as the "agency's best estimate of the price generally and currently paid by providers." (*See, e.g.*, Lavine Decl. at Ex. USAbt-K, D. Campana Dep. at 266-268 (Alaska); Ex. USAbt-C, S. Bridges Dep. at 29-31 (Arkansas); Ex. USAbt-D, A. Chapman Dep. at 307:4-310:16 (Colorado); Ex. USAbt-E, J. Dubberly Dep. at 39-42 (Georgia); Ex. USAbt-F, J. Parker Dep. at 32-34 (Illinois); Ex. USAbt-H, G. Cheloha Dep. at 350-353 (Nebraska); Ex. USAbt-P, M. Clifford Dep. at 209-210 (New Hampshire); Ex. USAbt-Q, E. Vaccaro Dep. at 35 (New Jersey); Ex. USAbt-R, L. Weeks Dep. at 32-34 (North Carolina); Ex. USAbt-AA, J. Young Dep. at 54 (Rhode Island); Ex. USAbt-V, L. Iverson Dep. at 162 (South Dakota); Ex. USAbt-J, A. Rugg Dep. at 366 (Vermont); Ex. USAbt-S, B. Tomlinson Dep. at 31-33 (Virginia); Ex. USAbt-Z, R. Homar Dep. at 390 (Wyoming); and Ex. USAbt-U, A. Hautea-Wimpee Dep. at 69:9-71:22 (Washington)).

58. Many State Medicaid program employees testified that they understood AWP to be defined according to its plain meaning (*see, e.g.*, Ex. USAbt-C, S. Bridges Dep. at 63-64 (Arkansas)); that they understood AWP to be "an average of wholesale prices for a particular product" (Ex. USAbt-Q, E. Vaccaro Dep. at 70-72 (New Jersey)); that they believed there was a predictable relationship between the published AWPs and actual market prices (*see, e.g.*, Ex. USAbt-H, G. Cheloha Dep. at 341 (Nebraska); Ex. USAbt-O, L. Farrand Dep. at 282-284, and

Ex. USAbt-P, M. Clifford Dep. at 203 (New Hampshire); and Ex. USAbt-J, A. Rugg Dep. at 357-358 (Vermont)).

59. State Medicaid programs required accurate, current and comprehensive pricing information in order to process many hundreds of thousands if not millions of claims for reimbursement on many thousands of different products. (Henderson Common Exhibit 10 (9/23/2008 Hillblom Dep. (California)), at 94:22 - 95:18); Henderson Common Exhibit 11 (12/15/2008 Dubberly Dep. (Georgia)), at 61:5-62:16; Henderson Common Exhibit 12 (11/18/2008 Parker Dep. (Illinois)), at 62:5 - 64:9, 67:5 -68:16; Henderson Common Exhibit 13 (12/3/2008 Cheloha Dep. (Nebraska)), at 341:7 - 346:18; Henderson Common Exhibit 14 (12/2/2008 Vaccaro Dep. (New Jersey)), at 70:3 -72:13; Henderson Common Exhibit 15 (12/15/2008 Stevens Dep. (New Mexico)), at 312:4 -315:22; Henderson Common Exhibit 16 (10/21/2008 Weeks Dep. (North Carolina)), at 101:2 - 104:21; Henderson Common Exhibit 17 (12/15/2008 Rugg Dep., (Vermont)), at 357:1 - 358:22; Henderson Common Exhibit 18 (12/4/2008 Hayashi Dep. (Virginia)), at 27:6 -29:11)

60. State Medicaid programs relied on published average wholesale prices (AWPs) and, in some cases, published wholesale acquisition costs (WACs) to estimate acquisition costs and process claims for reimbursement. It would not have been possible for States to process Medicaid claims without relying on AWPs and WACs published by the compendia. (Henderson Common Exhibit 19 (12/10/2008 Bridges Dep. (Arkansas)), at 43:16 - 44:21, 63:12 - 64:17; Henderson Common Exhibit 20 (12/9/2008 Fine Dep. (Maryland)), at 48:11 - 50:15; Henderson Common Exhibit 13 (12/3/2008 Cheloha Dep. (Nebraska)), at 341:12 - 345:11, 348:12 - 350:10; Henderson Common Exhibit 21 (10/28/2008 Farrand Dep. (New Hampshire)), at 282:7 - 284:22;

Henderson Common Exhibit 22 (10/29/2008 Clifford Dep. (New Hampshire)), at 203:9 - 203:12; Henderson Common Exhibit 14 (12/2/2008 Vaccaro Dep. (New Jersey)), at 70:3 -72:16; Henderson Common Exhibit 16 (10/21/2008 Weeks Dep. (North Carolina)), at 43:2 - 44:22; Henderson Common Exhibit 17 (12/15/2008 Rugg Dep.(Vermont)), at 358:1 - 358:22; Henderson Common Exhibit 23 (11/24/08 Hautea-Wimpee Dep. (Washington)), at 137:1 - 138:21)

61. State Medicaid officials never told manufacturers that they understood or approved of manufacturers reporting inflated AWPs. (*See, e.g.*, Lavine Decl. at Ex. USAbt-L, K. Gorospe Dep. of Dec. 3, 2008 at 293-295 (California); Ex. USAbt-B, C. Denemark Dep. at 485:1-486:13 (Delaware); Ex. USAbt-E, J. Dubberly Dep. at 76-77 and 355-358 (Georgia); Ex. USAbt-I, R. Stevens Dep. at 322-323 (New Mexico); Ex. USAbt-T, M. Davis Dep. at 63:12-66:21, 68:8-70:12, and Ex. USAbt-U, A. Hautea-Wimpee Dep. at 141:17-144:10, 147:4-148:12, 155:18-161:13 (Washington)).

A. State Payment Methodologies

62. The firm Myers and Stauffer LC has provided support to the United States' expert witness Mark G. Duggan, Ph.D., in connection with the three cases being jointly litigated by the United States and VAC. As part of that support, Myers and Stauffer gathered information concerning the methodologies used by the Medicaid programs of 48 States and the District of Columbia (the Covered States) to reimburse pharmacy providers for prescription drugs. (Henderson Common Exhibit 24 (Declaration of Kristopher Knerr (Knerr Decl.) ¶¶ 4-12). The information gathered by Myers and Stauffer was described in a series of summaries of drug

payment methodologies for each state in the damages reports. The summaries and all supporting information were produced to Abbott in connection with the United States' expert disclosures.

63. Subsequent to those disclosures, Myers and Stauffer has updated the methodology summaries to reflect information obtained in discovery. (Henderson Common Exhibit 24 (Knerr Decl.), ¶¶ 13-14) All additional materials relied upon by Myers and Stauffer in connection with the updating of the methodology summaries were produced to Abbott on July 24, 2009. (*Id.*, ¶ 13)

64. In preparing the summaries, Myers and Stauffer relied upon (a) State Plan Amendments obtained from CMS through DOJ; (b) deposition testimony (including testimony from state officials regarding the actual implementation of the payment methodology), deposition exhibits, and documents produced by Covered States pursuant to subpoenas; (c) state statutes, regulations and declarations; (d) annual publications of the National Pharmaceutical Council (NPC), *Pharmaceutical Benefits Under State Medical Assistance Programs*, from 1990 through 2005/2006; (e) communications with officials of State Medicaid agencies; and (f) policy manuals, provider bulletins, and other similar materials available on state Medicaid agency websites. (Henderson Common Exhibit 24 (Knerr Decl.), ¶¶ 8-10 and 12-13)

65. The methodology summaries are Attachment 1 to Knerr Decl. The information in each summary accurately summarizes the underlying data that was gathered by Myers and Stauffer. (Henderson Common Exhibit 24, (Knerr Decl.), ¶ 5)

66. Currently all Covered States except for Indiana reimburse pharmacy providers for prescription drugs under a "lower of" methodology in which payment is made based, at least in part, on the lower of (a) the State's estimated acquisition cost (EAC) plus a dispensing fee, (b)

the pharmacy's usual and customary charge (U&C) (sometimes referred to as the "billed amount"), or (c) the Federal Upper Limit (FUL) established by CMS pursuant to 42 C.F.R. § 447.332; (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 18) Indiana recently eliminated the FUL from its methodology. (*Id.*)

67. For the period 1991 to the present, each Covered State used AWP as the primary basis for determining the EAC component of their drug payment methodology, during at least part of that period; 42 of the Covered States used AWP as the primary basis for determining the EAC component of their State's drug payment methodology for the entire time period of 1991 to present. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 24a). The remaining Covered States used WAC or a combination of AWP and WAC as the basis for determining the EAC component of their state's drug payment methodology. (*Id.*, ¶ 24b)

68. During the period 1991 to the present, only six Covered States have deviated from the methodology described in the paragraph 29, above: (1) Delaware used Actual Acquisition Cost before May 1, 1997; (2) Michigan used Actual Acquisition Cost, with a limit based on AWP, before September 15, 1995; and (3) Alaska, New York, Arkansas and Massachusetts, each for specific periods of time, did not include EAC in the "lower of" algorithms when the drug was subject to a FUL. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 19)

69. During the period 1991 to the present, 42 of the Covered States have implemented a State Maximum Allowable Cost (SMAC) (sometime under different names) feature. A SMAC is an upper limit established by the State, similar to the FUL, but often determined based on criteria different than the FUL. (Henderson Common Exhibit 24 (Knerr Decl.), ¶¶ 20, 24f) Twenty two of these Covered States have implemented a SMAC program during the entire time

period. (*Id*., ¶ 24f) In all of these Covered States, the SMAC program is incorporated into the "lower of" methodology described above, except that Hawaii does not apply the SMAC if an FUL is in place. (*Id*., ¶¶ 20, 24e-f)

70. Twenty-five Covered States add to their "lower of" algorithm, for at least some of the time period, the wholesale pricing information provided in 2000 by the Department of Justice and the National Association of Medicaid Fraud Control Units and published by First DataBank. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 21). Those prices are discussed herein at paragraphs 71 to 74.

71. On or around September 8, 2000, CMS sent Program Memorandum Transmittal AB-00-86 to Medicare Part B carriers, including the DMERCs, providing them with alternative wholesale price information developed jointly by the Department of Justice and the National Association of Medicaid Fraud Control Units (NAMFCU). (Abbott Exhibit AP (Thomas Exhibit 83); Roxane Tab 118 (Thomas Exhibit 84); Reid Dec. Exhibit 181 (Thomas Exhibit 85)) The price information covered 32 different drugs, including some of those at issue in the instant cases, compiled mainly from wholesaler catalogs. (*Id*. at 1) (The parties have referred to the alternative AWPs as the DOJ AWPs, although in reality the information consisted simply of prices considered generally and currently paid in the marketplace.) The Transmittal instructed the carriers to consider those alternate wholesale prices in determining Medicare reimbursement amounts. (*Id*.)

72. CMS did retract the September 2000 Program Memorandum. (November 17, 2000 Program Memorandum to Carriers and Intermediaries (Roxane Tab 121)(Thomas Exhibit 56)) However, it was not a rejection of the need for pricing information pricing information

reflective of what was generally and currently paid in the marketplace. A subsequent HCFA program memorandum made clear that the purpose was to give the General Accounting Office (GAO) time to review Medicare payment policies and to make specific recommendations to the Secretary and Congress as to how to revise drug payment methodologies. (May 3, 2001 Program Memorandum from HCFA to Carriers and Intermediaries (Abbott Exhibit BD) (Thomas Exhibit 86))

73. Indeed, the Benefits Improvement and Protection Act of 2000 arose out of efforts by Congress to stop what one representative termed "illegal behavior" and an "outrage." (Henderson Common Exhibit 9 (Medicare Payments for Currently Covered Prescription Drugs: Hearing before the Subcomm. on Health of the House Comm. on Ways and Means, 107th Cong. 7 (2002) (statement of Rep. Stark, Member, House Comm. on Ways and Means))

74. On September 21, 2001, the GAO issued the report as directed by Congress. The GAO report recommended:

> Establish Medicare payment levels for part-B prescription drugs and their delivery and administration that are more closely related to their costs. Payments for drugs should be set at levels that reflect actual market transaction prices and the likely acquisition cost to providers.

(Henderson Common Exhibit 39 (Payments for Covered Outpatient Drugs Exceed Providers' Costs, GAO-01-1118, September 21, 2001))

75. Forty-three Covered States use First DataBank or First DataBank together with Medispan or Red Book as their primary source of information for determining EAC. Of the remaining six Covered States, five use MediSpan as their primary source for determining EAC, and one State uses Red Book for determining EAC. Some Covered States have changed the compendia they use for their prescription pricing, as noted in the respective Myers and Stauffer

summaries. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 24c)

76. The following paragraphs 36 through 85, concerning the accuracy of State methodology summaries, refer to the summaries in Attachment 1 to the Knerr Decl. The "supporting materials" means the supporting materials referenced in ¶¶ 5 and 12-13 of the Knerr Declaration.

77. The summary for the State of Alabama is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

78. The summary for the State of Alaska is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

79. The summary for the State of Arkansas is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

80. The summary for the State of California is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

81. The summary for the State of Colorado is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

82. The summary for the State of Connecticut is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the

supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

83. The summary for the State of Delaware is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

84. The summary for the State of Florida is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

85. The summary for the State of Georgia is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

86. The summary for the State of Hawaii is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

87. The summary for the State of Idaho is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

88. The summary for the State of Illinois is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

89. The summary for the State of Indiana is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

90. The summary for the State of Iowa is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

91. The summary for the State of Kansas is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

92. The summary for the Commonwealth of Kentucky is a true and accurate summary of features of the prescription drug payment methodology of that Commonwealth, as documented in the supporting materials for that Commonwealth. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

93. The summary for the State of Louisiana is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

94. The summary for the State of Maine is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

95. The summary for the State of Maryland is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

96. The summary for the Commonwealth of Massachusetts is a true and accurate summary of features of the prescription drug payment methodology of that Commonwealth, as documented in the supporting materials for that Commonwealth. (Henderson Common Exhibit

24 (Knerr Decl.), ¶ 5)

97. The summary for the State of Michigan is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

98. The summary for the State of Minnesota is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

99. The summary for the State of Mississippi is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

100. The summary for the State of Missouri is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

101. The summary for the State of Montana is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

102. The summary for the State of Nebraska is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

103. The summary for the State of Nevada is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

104. The summary for the State of New Hampshire is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

105. The summary for the State of New Jersey is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

106. The summary for the State of New Mexico is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

107. The summary for the State of New York is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

108. The summary for the State of North Carolina is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

109. The summary for the State of North Dakota is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

110. The summary for the State of Oklahoma is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

111. The summary for the State of Oregon is a true and accurate summary of features

of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

112. The summary for the Commonwealth of Pennsylvania is a true and accurate summary of features of the prescription drug payment methodology of that Commonwealth, as documented in the supporting materials for that Commonwealth. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

113. The summary for the State of Rhode Island is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

114. The summary for the State of South Carolina is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

115. The summary for the State of South Dakota is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

116. The summary for the State of Tennessee is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

117. The summary for the State of Texas is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

118. The summary for the State of Utah is a true and accurate summary of features of

the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

119. The summary for the State of Vermont is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

120. The summary for the Commonwealth of Virginia is a true and accurate summary of features of the prescription drug payment methodology of that Commonwealth, as documented in the supporting materials for that Commonwealth. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

121. The summary for the State of Washington is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

122. The summary for the State of West Virginia is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

123. The summary for the State of Wisconsin is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

124. The summary for the State of Wyoming is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

125. The summary for the District of Columbia is a true and accurate summary of

features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

B. State Claims to the Federal Government For Federal Medicaid Monies

126. States request federal Medicaid funds on a quarterly basis. Henderson Common Exhibit 25 (Declaration of Kristin A. Fan (Fan Decl.), ¶ 5) The process generally begins 45 days before the upcoming quarter begins, with each state submitting to CMS a budget of what it projects the state will spend during the upcoming quarter. *Id*.; 42 C.F.R. § 430.30(b). The state Medicaid official provides the information electronically using a Form CMS-37. (*Id.*, ¶ 5) Along with the overall funding request, the state will provide estimates of various types of services, including drug costs. *Id*. Further, the CMS-37 includes a certification that states in part:

> The fiscal year budget estimates only include expenditures under the Medicaid program under title XIX of the Social Security Act (the Act), and as applicable, under the State Children's Health Insurance Program (SCHIP) under title XXI of the Act, that are allowable in accordance with applicable implementing Federal, state, and local statutes, regulations, policies, and the state plan approved by the Secretary and in effect during the fiscal year under title XIX of the Act for the Medicaid program, and as applicable, under title XXI of the Act for the SCHIP. The budget estimates are based upon the most reliable information available to the state.

Id.

127. A state's budget estimate for a given quarter is normally based on the state's Medicaid expenditures in prior quarters. (Henderson Common Exhibit 25 (Fan Decl.), ¶ 6) Therefore, if drug expenditures in prior quarters are improperly inflated, this would likely cause absent an adjustment, the budget estimate for a subsequent quarter to be inflated. *Id*.

128. The CMS 37 form is sent to the appropriate regional CMS office. (Henderson

Common Exhibit 25 (Fan Decl.), ¶ 7); 42 C.F.R. § 430.30(b), (d). Upon receipt, regional office staff will review the form and make recommendations to the CMS central office as to whether the state funding request should be approved, approved with adjustments, or denied. 42 C.F.R. § 430.30(d); *Id.*, ¶ 7) The CMS central office reviews the regional analyst's recommendations. (*Id.*, ¶ 7) In deciding what funding level to approve for the following quarter, the CMS central office "considers the State's estimates, the regional office recommendations and any other relevant information, including any adjustments to be made under paragraph (d)(2) of this section, and computes the grant." (*Id.*; 42 C.F.R. § 430.30(d)(2)) In determining whether any adjustments should be made under subsection (d)(2) of the regulation, the central office examines any expenditures from previous quarters. (*Id.*, ¶ 7; 42 C.F.R. § 430.30(d)(2)) Once the funding request is approved, the state can draw down the federal monies on a federal letter of credit for the allotted amount as costs are incurred. (*Id.*, ¶ 7) The State draws down federal funds through a commercial bank and the Federal Reserve System. *Id.*

129. Section 430.30(d)(3), 42 C.F.R., provides that the grant award "authorizes the State to draw Federal funds as needed to pay the Federal share of disbursements." It is CMS's position that the state's quarterly federal Medicaid award is only to be used to reimburse Medicaid providers for actual payments. (Henderson Common Exhibit 25 (Fan Decl.), ¶ 8) In practice, a state draws down federal funds as actual payments are made by the State to Medicaid providers, including pharmacies and physicians seeking payment for drugs. *Id.* Thus, if a state overpays providers because of false provider claims, the state's draw-down on the letter of credit for the federal share will be affected, unless an adjustment is made. (*Id.*, ¶ 8)

130. After each calendar quarter, the state must submit to CMS a reconciliation of its

actual Medicaid expenditures against the monetary advance made on the basis of the Form 37. 42 C.F.R. § 430.30(c). The state electronically submits this information using a Form CMS-64. A State submitting the Form CMS 64 makes a certification that includes the following:

> I certify that:
>
> 1. I am the executive officer of the state agency or his/her designate authorized by the state to submit this form.
>
> 2. This report only includes expenditures under the Medicaid program under Title XIX of the Social Security Act (the Act), and as applicable, under the State Children's Health Insurance Program (SCHIP) under Title XIX of the Quarter Ended indicated above under Title XXI of the Act.
>
> 3. The expenditures included in this report are based on the state's accounting of actual recorded expenditures, and are not based on estimates.

(Henderson Common Exhibit 25 (Fan Decl.), ¶ 9)

131. The CMS web site provides an explanation of the Form CMS-64. Centers for Medicare and Medicaid Services, Medicaid Budget and Expenditure System (Medicaid Quarterly Expense Report), available at http://www.cms.hhs.gov/MedicaidBudgetExpendSystem/02_CMS64.asp. It states in part:

> The amounts reported on Form CMS-64 and its attachments must be actual expenditures for which all supporting documentation, in readily reviewable form, has been compiled and is available immediately at the time the claim is filed. Form CMS-64 is a statement of expenditures for which states are entitled to Federal reimbursement under Title XIX and which reconciles the monetary advance made on the basis of Form CMS-37 filed previously for the same quarter. Consequently, the amount claimed on the Form CMS-64 is a summary of expenditures derived from source documents such as invoices, cost reports and eligibility records.

(Henderson Common Exhibit 25 (Fan Decl.), ¶ 10)

132. The information in the Form CMS-64 is a source of information used in adjusting

future Form-37 funding requests. (Henderson Common Exhibit 25 (Fan Decl.), ¶ 11; 42 C.F.R. § 430.30(d)(2)) If CMS believes that it has overpaid a state based on its review of the Form-64, or otherwise, CMS may adjust future authorizations to offset the overpayment or seek to recover the amount overpaid. (42. U.S.C. § 1396b(d)(5); *Id.*, ¶ 11) While federal funding is made available prospectively to state Medicaid programs, the quarterly funding level for a state's Medicaid program is directly determined based on the state's actual, quarterly Medicaid expenditures. (*Id.*, ¶ 11)

C. The Role of Price Compendia in Medicaid Drug Payment

133. Many third-party payors, including state, federal government and private health plans, use database products from national drug pricing compendia in determining their payment levels for drugs eligible for payment under their benefit plans. (Henderson Common Exhibit 24 (Knerr Decl.), ¶¶ 25-84;) *See In re Pharmaceutical Industry Average Wholesale Price Litigation*, 263 F. Supp. 2d 172, 178 (D. Mass. 2003)).

134. Plaintiff lists the AWPs published by FDB for Abbott's Ery products as contained in the exhibits attached to the Declaration of Ian Dew filed in Support of Plaintiffs Motion for Partial Summary Judgment. Abbott reported so-called "list prices" for these products to FDB, knowing and relying on FDB to make a known mathematical calculation to the list prices to determine an AWP for publication. Abbott knew that published AWPs were based on 125% of Abbott's reported WACs. Beth Garvin-Senger Tr. at 46-47 (Thomas Exhibit 1).

135. A corporate designee for one of the compendia publishers, Red Book, testified that the manufacturers controlled the prices published in the Red Book. Kristin Minne testified that AWP was a required Red Book field until early 2003. (Henderson Common Exhibit 26

(11/18/08 Minne Dep.), at 158:9 -159:1) AWPs were provided to Red Book by the Defendants, and those manufacturer-supplied AWPs were then entered into the pricing database. *(Id.*, 158:9 - 159:1) Annually, Red Book sends a Product Listing Verification (PLV) form to each manufacturer. *(Id*., 84:11-87:1) The PLV includes a print out of the manufacturer's drugs as they are currently listed by Red Book, and it requests that the manufacturer verify and confirm that their products' pricing information is accurate. *(Id*., 95:6 - 96:14)

136. As of early 2003, Red Book implemented a new AWP Policy, in which manufacturers were no longer required to report their AWPs. If they chose not to report an AWP, Red Book would calculate and publish an AWP based on a percentage markup from the manufacturer's reported WAC or DP. Manufacturers were notified of what this standard mark-up formula would be. (Henderson Common Exhibit 26 (11/18/08 Minne Dep.), at 159:11 - 160:1) Manufacturers choosing to report only a WAC or DP provided guidance to Red Book on how to calculate an AWP for their product. (*Id.*, 171:2 - 171:18). Abbott PPD continued to allow AWPs to be published for PPD drugs, including the Erys (April Gerzel Tr. 2/20/09 at 52-53 (Thomas Exhibit 35)).

VII. 2003 OIG COMPLIANCE PROGRAM GUIDANCE FOR PHARMACEUTICAL MANUFACTURERS

137. On October 3, 2002, the Office of Inspector General for the Department of Health and Human Services published "Draft OIG Compliance Program Guidance for Pharmaceutical Manufacturers." 67 Fed. Reg. 62057-62067 (Oct. 3, 2002). The Draft Guidance identified "major risk areas for pharmaceutical manufacturers: (1) Integrity of data used by state and Federal governments to establish payment . . . ." 67 Fed. Reg. at 62060. The Draft Guidance further stated:

> Many Federal and state health care programs establish reimbursement rates for pharmaceuticals, either prospectively or retrospectively, using price and sales data directly or indirectly furnished by pharmaceutical manufacturers. The government sets reimbursement with the expectation that the data provided are complete and accurate. The knowing submission of false, fraudulent, or misleading information is actionable. A pharmaceutical manufacturer may be liable under the False Claims Act, if government reimbursement (including, but not limited to, reimbursement by Medicare and Medicaid) for the manufacturer's product depends, in whole or in part, on information generated or reported by the manufacturer, directly or indirectly, and the manufacturer has knowingly (as defined in the False Claims Act) failed to generate or report such information completely and accurately.

67 Fed. Reg. at 62060.

138. On May 5, 2003, the Office of Inspector General for the Department of Health and Human Services published final "OIG Compliance Program Guidance for Pharmaceutical Manufacturers." 68 Fed. Reg. 23731-23743 (May 5, 2003). The Guidance identified "major potential risk areas for pharmaceutical manufacturers: (1) Integrity of data used by state and Federal governments to establish payment . . . ." 68 Fed. Reg. at 23732. The Guidance identified "Specific Risk Areas" for pharmaceutical manufacturers, including "[i]ntegrity of data used by state and Federal governments to establish payment amounts." 68 Fed. Reg. at 23733. The Guidance further stated:

> Many Federal and state health care programs establish or ultimately determine reimbursement rates for pharmaceuticals, either prospectively or retrospectively, using price and sales data directly or indirectly furnished by pharmaceutical manufacturers. The government sets reimbursement with the expectation that the data provided are complete and accurate. The knowing submission of false, fraudulent, or misleading information is actionable. A pharmaceutical manufacturer may be liable under the False Claims Act if government reimbursement (including, but not limited to, reimbursement by Medicare and Medicaid) for the manufacturer's product depends, in whole or in part, on information generated or reported by the manufacturer, directly or indirectly, and the manufacturer has knowingly (as defined in the False Claims Act) failed to

generate or report such information completely and accurately." *Id.*

VIII. CONFIDENTIALITY OF AMP AND URA INFORMATION

139. Pursuant to the Medicaid Drug Rebate Statute (Rebate Statute), pharmaceutical manufacturers (including Abbott) are required to enter into a national Medicaid Rebate Agreement with the CMS. 42 U.S.C. § 1396r-8(a)(1). Once a manufacturer enters a rebate agreement with CMS, state Medicaid programs are required, with certain limited exceptions, to reimburse providers for that manufacturer's drugs. 42 U.S.C. § 1396r-8(d).

140. Pursuant to the Rebate Statute, drug manufacturers (including Abbott) are required to calculate and submit AMPs to CMS on at least a quarterly basis. 42 U.S.C. § 1396r-8(b)(3) and (k)(1).

141. CMS administers the Rebate Statute in part by using a manufacturer's AMP information and drug utilization information submitted by States to calculate a "Unit Rebate Amount" (URA). 42 U.S.C. § 1396r-8(b)(2)(A). The URA is the unit amount computed by CMS to which the Medicaid utilization information may be applied by States in invoicing the Manufacturer for the rebate payment due.

142. The Rebate Statute requires that AMPs provided to CMS be kept confidential and not be disclosed by CMS except for the purpose of carrying out the purposes of the rebate program. 42 U.S.C. § 1396r-8(b)(3)(D). Abbott PPD employees understood that the AMPs would be kept confidential by the government. Beth Garvin-Senger Tr. 12/17/08 at 118:8 to 118:12 (Thomas Exhibit 1).

143. The specific rebate agreements entered into between CMS and Abbott states as follows:

> Pursuant to Section 1927(b)(3)(D) of the [Social Security] Act and this Agreement, information disclosed by the Manufacturer in connection with this Agreement is confidential and, notwithstanding other laws, will not be disclosed by the Secretary or State Medicaid Agency in a form which reveals the Manufacturer, or prices changed by the Manufacturer, except as necessary by the Secretary to carry out provisions of [the Rebate Statute].

(Roxane SOF, Tab 143, p. 9 (Thomas Exhibit 89); Reid Decl., Exhibit 34 (Thomas Exhibit 90))

144. In a 1995 proposed rulemaking published at 60 Fed. Reg. 48442 (1995), the Department of Health and Human Services stated as follows concerning AMP information:

> C. Confidentiality of Manufacturer Price Information
>
> Comment: Many of the commenters believed that States should not have access to manufacturers' price information, including unit rebate amounts, since HCFA has access to this information. The commenters stated that the risk of disclosure and use of information for other purposes is too great.
>
> Response: We have agreed not to disclose AMP and best price to States but maintain that the statute contemplates the disclosure of manufacturer pricing data to States. Section 1927(b)(3)(D) of the Act provides that information concerning drug prices must not be disclosed by "the Secretary or a State agency (or contractor therewith)." By including States within the confidentiality provisions, we believe that the Congress intended that States have the right to access of sufficient pricing information to calculate their rebates as required by the statute. The unit rebate amount, which provides the rebate due per tablet, etc., and which is the end result of the manufacturer's calculation, is, in our opinion, the minimum amount of information States need to accomplish this. At the same time, the statute protects the manufacturer's pricing data from disclosure. In accordance with section 1927(b)(3)(D) of the Act, information disclosed by manufacturers in connection with the rebate agreement is confidential and, notwithstanding other provisions of law (including the Freedom of Information Act, 5 U.S.C. 552) must not be disclosed by HCFA, the State agency, or its contractors in a form that reveals the manufacturer, except as necessary for the Secretary of HHS to carry out the provisions of section 1927 and for the Comptroller General or the Director of the Congressional Budget Office to review the information provided.

145. In an exchange of letters in October 1991 and May 1992 relating to the State of Hawaii's implementation of the Medicaid Rebate statute, HCFA requested, and Hawaii gave assurances that "the State will keep the unit rebate amount confidential and will not disclose it for purposes other than rebate invoicing and verification." (Henderson Common Exhibits 27 and 28)

146. On or about April 22, 2004, CMS approved a New Hampshire State Plan Amendment allowing the State to enter into the Michigan Multi-State Pooling Supplemental Drug Rebate Agreement. The SPA included the statement, "[t]he unit rebate amount is confidential and cannot be disclosed in accordance with Section 1927(b)(3)(D) of the Social Security Act." (Henderson Common Exhibit 29)

147. In a September 2001 "Medicaid Drug Rebate Operational Training Guide" prepared by CMS's Center for Medicaid and State Operations, the agency stated that AMPs:

> are generally subject to both privacy and trade secret restrictions and are not released by CMS and must not be released by states. The pricing data CMS receives is held in the strictest confidence, and must not be released by states. The pricing data CMS receives is held in the strictest confidence and maintained only on CMS's master files. CMS sends URAs to states, but actual pricing data goes no farther than CMS.

(Roxane SOF, Tab 142A, at D2) (Thomas Exhibit 91)

148. In a letter to the State of Texas dated May 3, 2004, CMS stated:

> You ask for confirmation that State Medicaid programs may not use the rebate information, including the Unit Rebate Amount (URA) and Reconciliation of State Invoice (ROSI) reports, to calculate an estimated acquisition cost (EAC) for reimbursement. You are correct. In light of the confidentiality provisions of Section 1927(b)(3)(D) of the Social Security Act, drug pricing information disclosed by manufacturers pursuant to the drug rebate provisions is confidential and shall not be disclosed by either the Secretary or the State.

(Henderson Common Exhibit 31)

149. In a statement submitted to the Subcommittee on Health Care of the Senate Finance Committee on or about March 14, 2002, CMS Administrator Thomas Scully stated, "We collect AMP data for Medicaid on one side of my agency. . . . But by statute we're not allowed to share that with the Medicare side of the agency. It's proprietary data just for the purpose of the Medicaid program. . . . . the law that created it prohibited us from using AMP for Medicare. . . . . AMP provides a pretty good source of data, but by statute it is limited to use for the Medicaid program and the Medicare side of my agency doesn't have access to it by law." "Reimbursement and Access to Prescription Drugs Under Medicare Part B," 107th Cong. 16, Hearing Before the Subcomm. on Health Care of the S. Finance Comm. (March 14, 2002) (statement of Thomas A. Scully), 2002 WL 399357 at *18-19.

150. Larry Reed, Technical Director in the Division of Pharmacy, CMS, testified regarding AMP information submitted by manufacturers, stating, "The information that we would get from the manufacturers would not be part of the reimbursement system. The information that we get from the manufacturers would be part of the rebate program, the AMP data, the best price data." (Henderson Common Exhibit 32 (10/2/08 Reed Dep.), at 1094:4-9)

151. Responsible officials at CMS testified that understood AMPs were confidential, and could only be used for purposes of the Rebate Program. *See, e.g.* (Henderson Common Exhibit 33 (9/26/2007 Reed Dep.), at 282:20 - 283:4; Henderson Common Exhibit 34 (9/27/2007 Reed Dep.), at 352:14 - 353:11; Henderson Common

Exhibit 35 (6/21/2007 Vladeck Dep.), at 457:19 - 460:20, 464:7 - 464:19, 584:21 - 586:4; Henderson Common Exhibit 36 (2/27/2007 Duzor Dep.), at 368:14 - 369:10)

152. AMPs were not utilized in the calculation of Federal Upper Limits, as AMPs were not listed in "published compendia." 42 C.F.R. § 447.332(a)(1)(ii); Henderson Common Exhibit 40 (Declaration of Susan Gaston), ¶ 6 [Exhibits omitted]. Persons responsible for setting FULs at CMS did not use AMPs, as AMPS are not listed in "published compendia." *Id.*; Henderson Common Exhibit 37 (3/19/2008 Gaston Dep.), at 528:4 - 529:1)

153. AMPs were on occasion provided to HHS, Office of the Inspector General, in furtherance of the OIG's mission to conduct audits and investigations, and to prevent and detect waste, fraud and abuse in the agency's programs and operations. 5 U.S.C. app. 3 §§ 2, 4, 8G (1988). However, responsible officials at OIG testified that they understood AMPs were confidential. (Henderson Common Exhibit 38 (2/6/2008 Vito Dep.), at 1196:10 - 1196:19) OIG and other governmental reports regularly referred to AMPs as confidential.

154. CMS did not instruct states to use AMPs for reimbursement. (Henderson Common Exhibit 33 (9/26/2007 Reed Dep.), at 281:16-22)

155. State Medicaid officials have testified that they understood that AMPs were confidential, and that they could not use AMP information in setting reimbursement rates. (Henderson Common Exhibit 19 (12/10/2008 Bridges Dep. (Arkansas)), p. 70:5 - 72:22; Henderson Common Exhibit 43 (12/3/2008 Gorospe Dep. (California)), at 283:8 - 284:21; Henderson Common Exhibit 11 (12/15/2008 Dubberly Dep. (Georgia)), at 83:20

- 86:18; Henderson Common Exhibit 12 (11/18/2008 Parker Dep. (Illinois)), at 72:2 - 74:8; Henderson Common Exhibit 21 (10/28/2008 Farrand Dep. (New Hampshire)), at 287:1 - 293:17; Henderson Common Exhibit 14 (12/2/2008 Vaccaro Dep. (New Jersey)), at 77:1 - 77:16, 102:18 - 103:19; Henderson Common Exhibit 16 (10/21/2008 Weeks Dep. (North Carolina)), at 112:8 -113:10; Henderson Common Exhibit 17 (12/15/2008 Rugg Dep. (Vermont)), at 373:1 - 373:20)

156. In a 2001 report, the OIG discussed the confidentiality of the AMPs as follows:

> Currently, CMS interprets the confidentiality clause very narrowly. This interpretation prevents CMS from sharing average manufacturer price data with State Medicaid agencies. The CMS reports only the unit rebate amounts to States, from which States cannot deduce AMP because of the complex unit rebate methodology. It would seem plausible, however, to interpret the confidentiality provision more broadly as a safeguard to prevent manufacturers from gaining access to the pricing information of their competitors. The legislation specifically prohibits the State Medicaid agencies from disclosing average manufacturer price and Best Price, which implies a legislative assumption that State Medicaid agencies would have access to that information. In September 1995, CMS addressed this issue in response to comments received on the proposed rule regarding Medicaid payment for outpatient drugs. The CMS asserted that they would not to disclose AMP to the States but maintained that the statute contemplates the disclosure of manufacturer pricing data to the States and that they believed Congress intended that States have access to sufficient pricing information to implement the Medicaid drug rebate program.

(Reid Dec. Exhibit 38 at 22) (Thomas Exhibit 92)

Respectfully submitted,

For the relator, Ven-A-Care of the
Florida Keys, Inc.,

/s/ James J. Breen
JAMES J. BREEN
The Breen Law Firm, P.A.
5755 North Point Parkway
Alpharetta, GA 30022
Phone: (770) 740-0008

/s/ Susan Schneider Thomas
SUSAN SCHNEIDER THOMAS
GARY L. AZORSKY
ROSLYN G. POLLACK
Berger & Montague, P.C.
1622 Locust Street
Philadelphia, PA 19103
Phone: (215) 875-3000
Fax: (215) 875-4604

C. JARRETT ANDERSON
Anderson, LLC
208 West 14th Street, Suite 3-B
Austin, TX 78701
Phone: (512) 469-9191